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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2014-0023]

New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification

Procedures: Response to Comments and Announcement of Implementation Schedule

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS or "the Agency") is announcing that it will begin assessing whether establishments meet the pathogen reduction performance standards for Salmonella and Campylobacter in raw chicken parts and not-ready-to-eat (NRTE) comminuted chicken and turkey products. It will also begin posting, based on FSIS sampling results and depending on the standard for the particular product, whether an establishment meets the FSIS pathogen reduction performance standards, or what category an establishment is in. This notice also responds to comments received on the January 2015 Federal Register notice that proposed the standards and announced

changes to FSIS's verification sampling program.

DATES: FSIS will begin assessing whether establishments meet the new pathogen reduction performance standards for chicken parts and comminuted chicken and turkey products on [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Also beginning no sooner than [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], FSIS will begin posting on its website the category status of all eligible establishments subject to the existing poultry carcass pathogen reduction performance standards based on sample results from May 2015 (when FSIS stopped set-based, consecutive day testing and began routine sampling throughout the year of broiler and turkey carcasses) to the present. See the **SUPPLEMENTARY INFORMATION** section for more information about implementation dates.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495, or by Fax: (202) 720-2025.

SUPPLEMENTARY INFORMATION:

Background

FSIS is responsible for verifying that the nation's commercial supply of meat, poultry, and egg products is safe,

wholesome, and properly labeled and packaged.

As FSIS explained in the January 26, 2015 (80 FR 3940), Federal Register notice ("January 2015 notice") in which the Agency proposed the new pathogen reduction performance standards, Salmonella and Campylobacter bacteria are among the most frequent causes of human foodborne illness in the United States. Currently, events that cause contamination of raw carcasses cannot be eliminated through the commercial production and slaughter practices employed by the U.S. industry. Contamination can be minimized, however, with the use of proper sanitary dressing procedures and by the application of interventions during slaughter and fabrication of the carcasses into parts and comminuted product.

Significantly, even though FSIS set standards for ground turkey and chicken in 1996 (61 FR 38806; July 25, 1996), the Agency has not set standards for other comminuted chicken and turkey products. These products have been associated with outbreaks (see 77 FR 72686; December 6, 2012). In addition, the Agency has not set a standard for chicken parts even though about 80 percent of chicken product is in the form of raw chicken parts fabricated from broiler carcasses (80 FR at 3941; January 26, 2015).

In the absence of standards, the Salmonella and Campylobacter present on raw poultry will survive on that product if it is not subjected to a full lethality treatment such as thorough cooking. In addition, cross contamination occurs when bacteria (such as Salmonella or Campylobacter) are spread from a contaminated source - a contaminated food or an infected food handler- to other foods or objects in the environment (80 FR 3940; January 26, 2015). FSIS will monitor the sampling results and the Centers for Disease Control and Prevention (CDC) illness data to evaluate the industry's progress in reducing product contamination and reducing illnesses.

A reduction in illness rates should result from the implementation of these performance standards because a smaller proportion of raw chicken parts and NRTE comminuted chicken and turkey products will likely be contaminated with Salmonella and Campylobacter than has been the case without standards (80 FR at 3942; January 26, 2015).

Recognizing the need for standards, FSIS began sampling and testing NRTE comminuted chicken and turkey products on June 1,

2013.¹ The Agency posted the aggregate results of this testing as part of its quarterly Salmonella report.²

In addition, FSIS conducted the Nationwide Microbiological Baseline Data Collection Programs: Raw Chicken Parts Baseline Survey, from January 2012 to August 2012, to estimate the percent positive of various raw chicken parts sampled and the levels of Salmonella, Campylobacter, and indicator bacteria on these products. FSIS used this information to estimate the national prevalence of Salmonella and Campylobacter in four pound portions of raw chicken parts. An overview of the Raw Chicken Parts Baseline Survey is available at http://www.fsis.usda.gov/wps/wcm/connect/a9837fc8-0109-4041-bd0c-729924a79201/Baseline_Data_Raw_Chicken_Parts.pdf?MOD=AJPERES.

In the January 2015 notice, FSIS also announced and requested comment on proposed pathogen reduction performance standards for Salmonella and Campylobacter in raw chicken parts and NRTE comminuted chicken and turkey products (80 FR at 3946; January 26, 2015). FSIS developed these proposed standards using the baseline data for parts and the on-going sampling data

¹ This sampling and testing for Salmonella and Campylobacter did not include heat-treated NRTE comminuted chicken or turkey.

² <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/quarterly-reports-salmonella>.

for NRTE comminuted chicken and turkey products. It also factored in what reduction in these two pathogens would be necessary to meet the Healthy People 2020 (HP2020) goals. The Agency developed Salmonella performance standards that would achieve at least a 30 percent reduction in illness rates from Salmonella for chicken parts, comminuted chicken, and comminuted turkey. FSIS developed a Campylobacter standard for chicken parts and comminuted chicken that it estimated would achieve a 33 percent reduction in illness rates.

Because FSIS found the prevalence for Campylobacter in 325 gram samples of comminuted turkey to be especially low, the highest practical reduction in illness rates for this product without establishing a zero-tolerance standard was estimated to be 19 percent. So, the reduction in illness rates estimated for the proposed standard for this one product-pathogen pair was less than the Healthy People goal of a 33-percent reduction (80 FR at 3942; January 26, 2015).

In the same Federal Register notice, for all FSIS-regulated products subject to Salmonella and Campylobacter verification testing, FSIS announced that it would begin using routine, random sampling throughout the year rather than the set-based consecutive day approach that it had used in the past

(80 FR at 3945; January 26, 2015), and that it would assess performance using a moving window of FSIS sampling results (80 FR at 3946). FSIS explained that it intended to collect samples on a weekly basis in high volume establishments and less frequently in lower volume establishments. In addition, FSIS announced that it would begin exploratory sampling of raw chicken parts (80 FR at 3945), raw pork products (80 FR at 3942), and imported raw poultry products (80 FR at 3944).

Finally, FSIS announced that it intended to post the category status for all eligible establishments because web-posting provides the public with the tools and information it needs to make informed food safety decisions (80 FR at 3948). Because a pathogen reduction performance standard already exists for young chicken (broiler) and turkey carcasses, FSIS announced that it would begin web-posting individual establishment category information for these establishments after it had considered the comments it received. FSIS stated that it would assess what category these establishments are in using combined historical set data and sample results beginning March 2015.

In response to a coalition of trade associations that requested that FSIS extend the comment period to provide additional time to formulate meaningful comments, FSIS extended

the comment period by an additional 60 days to May 26, 2015 (80 FR 12618; March 10, 2015).

The coalition also requested that FSIS extend all implementation dates announced in the January 2015 notice. The Agency did not delay implementation of all actions announced in the January 2015 notice because FSIS made available much of the information in that notice in other Federal Register notices.³ Therefore, in March 2015, FSIS began sampling raw chicken parts to gain information on the prevalence of Salmonella and Campylobacter (in four pound sample units) of those products and to gain experience in scheduling, collecting, and analyzing raw chicken parts for these pathogens.⁴ In April 2015, FSIS began sampling raw pork products for pathogens of public health concern, as well as for indicator organisms.⁵ In May 2015, FSIS began routine sampling, rather than set-based consecutive day sampling, of young chicken (broiler) and turkey carcasses.⁶ FSIS began sampling imported poultry carcasses, imported raw chicken parts, and imported NRTE comminuted chicken and turkey for

³ 78 FR 53017; Aug. 28, 2013, and 79 FR 32436; Jun. 5, 2014

⁴ FSIS Notice 16-15; <http://www.fsis.usda.gov/wps/wcm/connect/5233e84c-f4a6-4959-b861-926a4d912eff/16-15.pdf?MOD=AJPERES>.

⁵ FSIS Notice 23-15; <http://www.fsis.usda.gov/wps/wcm/connect/41f2bd6b-2c06-4384-935d-2ac31e3e77e9/23-15.pdf?MOD=AJPERES>

⁶ FSIS Notice 22-15; <http://www.fsis.usda.gov/wps/wcm/connect/3379df49-cc8d-47f7-83c3-d4d802668f6c/22-15.pdf?MOD=AJPERES>

Salmonella and Campylobacter in July 2015.⁷ FSIS has begun posting aggregate results from this testing as part of its quarterly Salmonella report.⁸

Because FSIS needed additional time to fully evaluate the comments submitted on posting information on establishment performance under the standards, FSIS did delay, and has yet to web-post, individual establishment information for establishments subject to poultry carcass sampling. On August 14, 2015, FSIS announced that it was temporarily removing the Category 3 list from its Web site until the new moving window sampling procedure is fully implemented.⁹

Final Performance Standards, Follow-up Sampling, Food Safety Assessments, and Establishment Posting

FSIS will begin assessing whether establishments meet the new pathogen reduction performance standards on [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. The new standards are:

Product	Max. Acceptable Percent Positive	Performance standard*
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⁷ FSIS Notice 32-15; <http://www.fsis.usda.gov/wps/wcm/connect/41a60d0e-060e-479c-a2c0-4096d8a542f2/32-15.pdf?MOD=AJPERES>

⁸ <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/quarterly-reports-salmonella>

⁹ <http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-updates/archive/2015/ConstUpdate081415>.

	<u>Salmonella</u>	<u>Campylobacter</u>	<u>Salmonella</u>	<u>Campylobacter</u>
Comminuted Chicken (325g sample)	25.0%	1.9%	13 of 52	1 of 52
Comminuted Turkey (325g sample)	13.5%	1.9%	7 of 52	1 of 52
Chicken Parts (4lb. sample)	15.4%	7.7%	8 of 52	4 of 52

* FSIS intends to interpret results within a moving window comprising fewer than 52 samples (n) by establishing a number of positive samples (s) such that $(s-1)/n < p \leq s/n$, where p is the maximum percent positive that would meet the performance standards.

These standards are the same as what FSIS proposed in the January 2015 notice.

Following publication of that notice, FSIS continued sampling and testing comminuted poultry products for Salmonella and Campylobacter. Also, as noted above, FSIS implemented ongoing sampling and testing of chicken parts for Salmonella and Campylobacter. FSIS found no notable difference between the results from this testing and the earlier test results for comminuted product and the chicken parts baseline results. Therefore, FSIS has made no changes to the standards based on these additional test results.

In addition, consistent with the January 2015 notice, FSIS will collect samples based on the volume of production at an

establishment. FSIS will sample eligible product from the largest-volume establishments four or five times per month (once per week), on average, and will decrease incrementally the number of samples it collects from establishments producing less volume. FSIS may sample a small number of establishments up to six times per month. The frequency will be determined on the basis of their production volume and history of sampling results.¹⁰ Establishments likely to get six samples are those that produce high volumes of several products. Furthermore, FSIS will attempt to collect at least the minimum number of samples outlined in the chart below per year in order to assess process control in all establishments subject to performance standards.

Product	Minimum number of samples to assess process control in a moving window	
	<u>Salmonella</u>	<u>Campylobacter</u>
Broiler Carcass	11	10
Turkey Carcass	14	19
Comminuted Chicken	10	52
Comminuted Turkey	10	52
Chicken Parts	10	13

¹⁰ <http://www.fsis.usda.gov/wps/wcm/connect/99b43489-0e14-40c0-b13e-53163d68bf1f/Sampling-Program-Plan-FY2016.pdf?MOD=AJPERES>

Because the Salmonella performance standard for broiler carcasses is 9.8 percent positive or less, FSIS has changed the minimum number of Salmonella samples to assess process control in a moving window for broiler carcasses to eleven. The minimum number identified in the January 2015 notice (10) would have effectively allowed zero positives. This would have constituted a zero tolerance standard. FSIS did not want to create a zero tolerance standard but did want to maintain the level of precision that underlay the proposal. FSIS accomplished this by increasing the minimum number of samples collected for Salmonella on broiler carcasses by one.

Consistent with what FSIS announced in the January 2015 Federal Register notice, the moving window for all products will be 52 weeks. However, the number of samples collected in the window can vary, depending on the volume of the product the establishment produces, and depending on whether FSIS collects follow up samples in response to an establishment not meeting the standard. Therefore, FSIS will assess establishment performance based on the maximum acceptable percent positive.

Because the comminuted chicken and turkey pathogen reduction performance standards permit only one positive result for Campylobacter in order to pass the standard, essentially

eliminating Category 2, FSIS will only categorize eligible establishments producing these products as either passing or failing. FSIS will categorize establishments following the criteria below:

I. Category 1. Consistent Process Control: Establishments that have achieved 50 percent or less of the Salmonella or Campylobacter maximum allowable percent positive during all completed 52-week moving windows over the last three months.

II. Category 2. Variable Process Control: Establishments that meet the Salmonella or Campylobacter maximum allowable percent positive for all completed 52-week moving windows but have results greater than 50 percent of the maximum allowable percent positive during any completed 52-week moving window over the last three months.

III. Category 3. Highly Variable Process Control: Establishments that have exceeded the Salmonella or Campylobacter maximum allowable percent positive during any completed 52-week moving window over the last three months.

IV. Passing. Establishments that meet the Campylobacter maximum allowable percent positive for NRTE comminuted chicken or turkey during all completed 52-week moving windows over the last three months.

V. Failing. Establishments that have exceeded the Campylobacter maximum allowable percent positive for NRTE comminuted chicken or turkey during any completed 52-week moving window over the last three months.

Note that when FSIS collects multiple samples within a week, all

those samples will be included in the window for that week.

In the January 2015 notice, FSIS stated that it intended to determine categories based on moving windows over the last six months. FSIS is changing this timeframe to every three months to provide more timely information on the establishment's status. As FSIS explained in the January 2015 notice, FSIS has determined that a 6-month time component will have minimal impact on the categorization of establishments that are most likely to meet the standard (80 FR at 3947). Similarly, the 3-month time component will have minimal effect on establishments that are most likely to meet the standard.

As part of its verification sampling program, consistent with its exploratory sampling program for comminuted product, FSIS will collect finished NRTE ground chicken and turkey and other types of NRTE comminuted chicken and turkey products. FSIS will not sample dumplings, wontons, egg rolls, or other comminuted chicken or turkey products wrapped in dough or other similar covering at this time. However, FSIS will sample raw sausage in casing.

FSIS will continue to sample mechanically separated chicken and turkey that is not intended to be processed into a ready-to-eat (RTE) product in a domestic official establishment, just as

it has done during the on-going exploratory testing. At this time, mechanically separated poultry will not be subject to the pathogen reduction performance standard for comminuted poultry. Given that mechanically separated chicken and turkey are not typically added to NRTE comminuted poultry products, results for these products were not used in developing the Salmonella contamination distribution used in the risk assessment (80 FR at 3943; January 26, 2015).

FSIS may consider implementing a pathogen reduction performance standard for mechanically separated poultry in the future, particularly if there is evidence that this product is being used in domestic NRTE product available to consumers, if the FSIS results for this product exhibit an unchanged or upward trend in positives, or if there is evidence that industry is not taking steps to reduce contamination of source carcass frame materials within the year following the publication of this notice. FSIS is concerned about the ongoing wholesomeness of this product if establishments do not take steps to reduce the high frequency of contamination of mechanically separated

poultry,¹¹ even if it is to be used in a finished product that is RTE. FSIS recommends that the industry at least begin implementing quality control procedures for ensuring that extraneous materials, including intestinal tract and other internal organ fragments, do not contaminate the source carcass frames regardless of whether or not the product is destined for RTE processing. These steps, at a minimum, will better ensure the wholesomeness of the product.

Consistent with the January 2015 notice, FSIS will sample the following chicken parts to assess whether they meet the standards: legs (comprised of the drumstick and thigh portions either separately or combined), wings, and breasts.

Also, consistent with what it announced in the January 2015 notice, as soon as practical after [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], FSIS will begin sampling 3-4 times per year product that has been excluded from Salmonella verification testing: chicken in poultry slaughter establishments operating under a religious exemption; the minor species carcasses under FSIS jurisdiction and inspection (species other than chicken, turkey, pork, and cattle, such as

¹¹ From January 1, 2015, through March 31, 2015, the percent positive rate for Salmonella in mechanically separated chicken was 88.52 percent and for mechanically separated turkey was 52.78 percent. (Available at <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/quarterly-reports-salmonella/quarterly-progress-reports>.)

squab, ratites, goose and lamb); and product otherwise eligible for sampling that FSIS has excluded because it is produced in low volume establishments that produce 1,000 pounds or less per day. FSIS expects to eventually implement pathogen reduction performance standards to assess process control for these products. However, before FSIS begins using these sample results to assess whether establishments previously excluded from verification sampling meet performance standards, it will provide notice and request comment on such standards in the Federal Register. Meanwhile, FSIS will treat these sample results as separate populations and report the aggregate results quarterly, including such information as percentage positive at the 25th, 50th, and 75th percentile.

No sooner than [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN FEDERAL REGISTER], FSIS will begin web-posting the category status of all establishments subject to the existing poultry carcass pathogen reduction performance standards. At that time, FSIS will post these establishments' Salmonella and Campylobacter category status based on sample results from May 2015 (when FSIS began routine sampling of broiler and turkey carcasses) to the present.

After completion of the first year of sampling (i.e., the

first 52-week moving window), for chicken parts and comminuted poultry products subject to sampling under the new pathogen reduction performance standards, FSIS will begin web-posting whether, based on FSIS results, the establishment is passing, or what category the establishment is in, depending on the standard for the particular product. However, based on at least the minimum number of samples to assess process control for that product/pathogen pair and other available information about establishments, such as noncompliance rates, if establishment performance overall does not improve or appears to be worsening before the completion of the first moving window, FSIS may begin web-posting individual establishment category information sooner.

In the January 2015 notice, FSIS announced that it intended to web-post the categories for all establishments subject to the Campylobacter pathogen reduction performance standards. However, because, as comments pointed out, the comminuted chicken and turkey pathogen reduction performance standards permit only one positive result for Campylobacter in order to pass the standard, essentially eliminating Category 2, FSIS will not, at this time, web-post the category status of individual establishments that do not meet the Campylobacter standard for comminuted chicken or

turkey products (i.e., those in Category 3). Instead, FSIS will web-post whether the eligible establishment is passing or failing. Consistent with the January 2015 notice, FSIS will update individual establishment postings on a monthly basis.

Starting [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN FEDERAL REGISTER], FSIS will web-post quarterly aggregate information relative to categories for all establishments subject to sampling under the new performance standards for which FSIS has collected the minimum number of samples, using the most recent sample results. This information will be aggregated and will not single out any specific establishment. This information will give industry and other stakeholders timely information about progress being made to reduce contamination in NRTE poultry of all types sampled. FSIS will also web-post calendar year prevalence estimates in its Salmonella and Campylobacter annual report. Results of follow-up sampling will be excluded for the purposes of these prevalence estimates. FSIS will not include follow-up sampling in prevalence estimates because these samples are non-random and targeted.

FSIS will schedule a Public Health Risk Evaluation (PHRE), and possibly a Food Safety Assessment (FSA), based on FSIS test

results, for establishments that do not meet the pathogen reduction performance standards; for establishments that have produced products with repetitive Salmonella or Campylobacter serotypes of public health concern or repetitive antibiotic resistant Salmonella; and for establishments with Salmonella or Campylobacter pulsed-field gel electrophoresis (PFGE) (or whole-genome sequencing, as it becomes available) patterns matching those found in recent outbreaks or epidemiologically linked to illnesses. FSIS intends to do the PHRE because it can reasonably be inferred that establishments in these categories have not adequately addressed Salmonella or Campylobacter in their Hazard Analysis and Critical Control Point (HACCP) systems. Based on PHRE analysis, FSIS will determine whether to schedule a FSA¹² at the establishment.

FSIS will collect 16 or 8 follow-up samples (depending on the product volume) on a daily or per shift basis, as soon as possible after an establishment has not met a pathogen reduction performance standard. The follow-up samples will count towards the samples collected as part of the moving window procedure for that establishment. In the January 2015 notice, FSIS stated that

¹² The purpose of an FSA is to assess and analyze an establishment's food safety system to verify that the establishment is able to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements.

it did not intend to count the follow up samples in the moving window for assessing whether establishments are meeting the standards. FSIS has decided to change its approach so that it can more quickly assess whether establishments have regained process control, and because, when establishments have regained control, FSIS believes their posted category status should reflect that fact. FSIS is also making this change in response to comments.

As we currently do for outbreak investigations, for at least 90 days after an establishment has not met a standard, FSIS will monitor CDC PulseNet database for matching food isolates to those obtained by FSIS in its sampling of products produced by the establishment. This monitoring will give FSIS early warning if an outbreak involving the establishment's products is developing. Moreover, as new tools such as whole genome sequencing become available, FSIS will also search for official sequencing databases matches between FSIS-regulated NRTE products and human illness. FSIS will alert its public health partners when an establishment does not meet the standard, so that they can also be on the lookout for an emerging outbreak. In addition, FSIS may collect the consignee list for product produced when an establishment has not met the

standard so that the Agency can focus its attention on the area in which the product was distributed.

Consistent with existing practices,¹³ after notifying an establishment that it has not met a performance standard, FSIS will conduct an assessment of the establishment's HACCP plan and Sanitation Standard Operating Procedures, through a PHRE, focusing on the establishment's planned corrective actions. In addition, FSIS will develop a plan to verify whether the establishment implemented corrective actions. FSIS may also conduct a FSA, when it deems it appropriate. If, after 90 days, the establishment has not been able to gain process control, as determined from FSIS's follow-up sampling and from the results of the PHRE or FSA, and the establishment has not taken corrective actions, FSIS will likely take enforcement actions, such as by issuing a Notice of Intended Enforcement (NOIE) or by suspending inspection, under the conditions and according to the procedures described in 9 CFR part 500. FSIS will not issue an NOIE or suspend inspection based solely on the fact that an establishment did not meet a performance standard.

If the establishment produced product associated with an

¹³ FSIS stated in a Federal Register notice published April 16, 2003 (68 FR 18593), that it was using Salmonella sample-set failures as an indication that there is something wrong in the establishment's HACCP system, and that the system needs to be carefully evaluated by the Agency.

outbreak, even if the establishment is in category 1, FSIS will scrutinize its corrective actions with particular care, including performing an Incident Investigation Team review (see FSIS Directive 5500.3).

Generally, if an establishment produces product associated with an outbreak or has failed to meet a pathogen reduction performance standard for Salmonella or Campylobacter and has not addressed those hazards in its HACCP plan, the establishment would need to reassess its HACCP plan for that product to determine whether the plan needs to be modified to address the hazard (9 CFR 417.3(b)). Thus, the establishment, to maintain an adequate HACCP system, will have to address the pathogen in its HACCP plan, rather than through a prerequisite program like the Sanitation Standard Operating Procedures.

Finally, consistent with FSIS testing of imported beef and poultry products for pathogens, FSIS will begin testing imported pork for Salmonella later in Fiscal Year 2016 (FY2016).

Summary of Implementation Dates

FSIS will begin assessing whether establishments meet the new pathogen reduction performance standards for chicken parts and comminuted chicken and turkey products on [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Also

beginning no sooner than [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], FSIS will begin posting on its website the category status of all eligible establishments subject to the existing poultry carcass pathogen reduction performance standards based on sample results from May 2015 (when FSIS stopped set-based, consecutive day testing and began routine sampling throughout the year of broiler and turkey carcasses) to the present. After completion of the first moving window of product sampled under the new pathogen reduction performance standards for chicken parts, comminuted chicken, and turkey products (approximately 1 year from publication of this notice), FSIS will begin web-posting whether individual establishments are in Category 1, 2, or 3, or whether they are passing the standards (in the case of NRTE comminuted chicken or turkey for Campylobacter). However, based on at least the minimum number of samples to assess process control for that product/pathogen pair and other available information about establishments, such as noncompliance rates, if establishment performance overall does not improve or appears to be worsening before the completion of the first moving window, FSIS may begin web-posting individual establishment category information sooner. As soon as practical after [INSERT DATE 90 DAYS AFTER

DATE OF PUBLICATION IN THE FEDERAL REGISTER], FSIS will begin sampling 3-4 times per year the following products which have been excluded from Salmonella verification testing: Broilers produced in poultry slaughter establishments operating under a religious exemption, minor species carcasses (minor species are those other than classes of chicken, turkey, pork and beef for which FSIS has previously set pathogen reduction performance standards and that are produced and consumed in larger quantities than other classes of these species or other species under FSIS jurisdiction and inspection, such as squab, ratites, lamb, and goose), and product from low volume establishments that produce up to 1,000 pounds per day of poultry product subject to sampling. This fiscal year, FSIS will also begin sampling imported pork products for Salmonella.

Summary of Comments and Responses

In the January 2015 notice, FSIS requested comment on specific issues: the proposed pathogen reduction performance standards for Salmonella and Campylobacter in raw chicken parts and NRTE comminuted chicken and turkey products; sampling of raw chicken parts that have been marinated or injected; the Agency's implementation strategy, including how it plans to assess process control in low volume establishments and the planned

modifications to its categorization system; how it plans to web-post the category status of eligible establishments; and the accuracy of the information and assumptions used in its cost-benefit analysis. FSIS received 15 comments in response to these and other issues in the notice. The comments were from consumer advocacy groups, organizations representing the meat/poultry industry, meat/poultry processors, a food ingredient supplier, and an individual.

FSIS has summarized and responded to the relevant issues raised by commenters below.

A. General Comments on Actions Announced in the Notice

Comments: Many comments from both industry and consumer groups supported FSIS establishing pathogen reduction performance standards for Salmonella and Campylobacter in NRTE chicken parts and comminuted chicken and turkey products because the commenters agreed that the standards are likely to benefit public health. In addition, many comments supported FSIS replacing set-based, consecutive-day sampling with routine sampling, including weekly sampling in high volume operations, and using a moving window approach for assessing process control to gain a better sense of ongoing establishment performance. Likewise, several comments supported FSIS using a more sensitive

enrichment-based method to analyze samples for Campylobacter, sampling imported raw chicken products, and sampling raw chicken parts other than breasts, legs, and wings to better understand the incidence of Salmonella and Campylobacter in these products and to assess whether additional performance standards may be needed. Finally, several comments supported FSIS's planned action to web-post the individual category status of establishments subject to FSIS sampling to assess whether they meet performance standards because it will provide the public with specific, geographical, and process capability information and will provide industry with incentives for making changes to their operations or from whom they purchase source materials.

Meanwhile, other commenters, mostly representing industry interests, generally were opposed to the issuance of new pathogen reduction performance standards and to web-posting individual establishment performance.

Response: FSIS has determined that it is prudent to issue of new pathogen reduction performance standards and to web-post establishment-specific performance as noted in detail below.

B. Proposed Performance Standards

Comment: An organization representing the chicken industry objected to the method and scientific evidence used to develop

the performance standards. Rather than use the Healthy People 2020 (HP2020) goals to set the standards, the organization argued that FSIS should identify the most significant sources of illnesses from these pathogens and focus its resources on these products. In addition, the organization argued that chicken and turkey are not the most significant sources of illnesses associated with these pathogens.

Response: The Healthy People Initiatives have served as a science-based framework for public health activities by FSIS, CDC, the Food and Drug Administration, and across other sections of the public health community for years. Furthermore, FSIS disagrees that the proposed pathogen reduction performance standards were not based on sufficient valid scientific evidence. Using a common analytical framework,¹⁴ FSIS developed the standards based on a variety of data sources, including Agency sampling data, the CDC foodborne illness and outbreak data, and the most recent available research, as well as the HP2020 national health objectives.

Recent research supports that poultry represents the largest fraction of Salmonella and Campylobacter illnesses

¹⁴ <http://www.fsis.usda.gov/wps/wcm/connect/afe9a946-03c6-4f0d-b024-12aba4c01aef/Effects-Performance-Standards-Chicken-Parts-Comminuted.pdf?MOD=AJPERES>

attributed to FSIS-regulated products.^{15,16,17} Furthermore, data from the National Antimicrobial Resistance Monitoring System (NARMS) show that the incidence of Salmonella in poultry products is five to ten times higher than that in ground beef or pork chops.¹⁸ Because FSIS can only directly affect those food commodities that fall under its jurisdiction, FSIS is addressing the product it regulates that poses the highest public health risk.

In addition, evidence of the connection of salmonellosis and contaminated NRTE comminuted poultry products can be found in the recent outbreaks that have been associated with these products. In 2011, there were two outbreaks involving ground turkey product. The 2011 Salmonella Hadar outbreak associated with turkey burgers sickened 12 people in 10 states and led to a recall of 54,960 pounds of turkey burger.¹⁹ The 2011 Salmonella Heidelberg outbreak associated with ground turkey product sickened 136 people in 34 states and led to one death.

¹⁵ Batz, M.B., et al. 2012. "Ranking the disease burden of 14 pathogens in food sources in the United States using attribution data from outbreak investigations and expert elicitation." J. Food Prot 75(7):1278-91.

¹⁶ Painter, J.A., et al. 2013. "Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998 – 2008." Emerg Infect Dis 19(3): 407 -15.

¹⁷ Interagency Food Safety Analytics Collaboration, 2015. "Foodborne Illness Source Attribution Estimates for Salmonella, Escherichia coli O157:H7, Listeria monocytogenes, and Campylobacter using Outbreak Surveillance Data."

¹⁸ Table 6 in NARMS. 2013. *Retail Meat Report 2011*. At:

<http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM334834.pdf>.

¹⁹ http://www.fsis.usda.gov/wps/wcm/connect/fsis-archives-content/internet/main/topics/recalls-and-public-health-alerts/recall-case-archive/archives/ct_index295a

Approximately 36 million pounds of ground turkey were ultimately recalled.²⁰ The CDC reported a 2013-2014 Salmonella Heidelberg illness outbreak associated with the consumption of chicken parts that sickened 634 people in 29 states and Puerto Rico.²¹

In addition, in 2015, the CDC investigated two separate outbreaks of Salmonella Enteritidis infections linked to raw, frozen, stuffed chicken entrees associated with two separate establishments that produced these products. These two outbreaks stemmed from poultry product in which the source materials were either comminuted chicken breast meat or whole chicken breast parts and resulted in twelve illnesses and five hospitalizations. In both outbreaks, the establishment involved did not consider implementing effective controls for the source materials or for the production process to know the frequency of contamination of source materials with Salmonella.

Thus, FSIS has concluded, using the available data and the public health science principles contained in a quantitative risk assessment, that adopting new pathogen reduction performance standards for comminuted poultry and chicken parts to reduce the Salmonella on these types of products would reduce

²⁰ <http://www.cdc.gov/salmonella/2011/ground-turkey-11-10-2011>

²¹ <http://www.cdc.gov/salmonella/heidelberg-10-13/>

consumer exposure to this pathogen and thus reduce the occurrence of illness.

Comment: An organization representing the turkey industry stated that the industry has already made great strides in lowering illness that, according to the commenter, FSIS did not account for in setting the standards. This organization also stated that it will be very difficult to achieve further reduction in illness through the proposed NRTE comminuted turkey product standards.

Response: FSIS agrees that the turkey industry, particularly, has collectively taken steps to reduce the incidence of pathogens in comminuted product following the Salmonella Heidelberg multistate outbreak in 2011 that infected more than 100 individuals. Nonetheless, setting pathogen reduction performance standards is an important tool in targeting reductions and in protecting public health, and FSIS has decided to proceed to do so.

In setting the performance standards, FSIS did not explicitly account for the decrease in pathogen contamination observed following the Salmonella Heidelberg outbreak. To do this, FSIS would have needed to use the most up-to-date attribution data. Given that there is about a two year lag in

the CDC outbreak data, it was not possible for the Agency to do so. FSIS did, however, use the most up-to-date published attribution data available (Painter et al., 2013). In addition, FSIS used the most recent contamination data available at the time it developed the performance standards (2013-2014). These contamination data reflect some of the reduction in pathogen contamination seen in comminuted turkey.

Still, FSIS recognizes that the performance standard for Campylobacter, allowing only one positive sample in the moving window, is quite rigorous. Regardless, such a performance standard is necessary to maintain industry focus on continuous improvement. However, as discussed later in this document, FSIS has agreed that, because the comminuted chicken and turkey pathogen reduction performance standards permit only one positive result for Campylobacter in order to pass the standard, there is no Category 2. Thus, FSIS will web-post these establishments as either passing or failing.

Comment: Several comments criticized the proposed pathogen reduction performance standards for comminuted poultry because they were not based on a full year of data. The commenters also stated that the standards were based on data from the high prevalence season for the pathogens.

Response: At the time that the pathogen reduction performance standards for comminuted poultry were developed and subsequently published, the standards were based on eight months of data. Meanwhile, FSIS has analyzed the first twelve months of data for NRTE comminuted chicken and turkey and compared the results to that of the 8-month analysis.²² FSIS found no notable difference between these results and earlier test results for comminuted product. Therefore, FSIS made no changes to the standards based on these additional test results.

However, FSIS acknowledges that setting the performance standards on data from a true high prevalence season (i.e., a period in which there was more frequent exposure of the public to pathogens of public health concern) could create an unintended consequence of permitting more exposure of the public to pathogens of public health concern during a true low prevalence season. FSIS's published analysis of seasonal patterns of Salmonella contamination in FSIS regulated products did not identify a significant seasonal pattern in ground chicken or turkey.²³ Therefore, FSIS concludes that the

²² Additional data is available at <http://www.fsis.usda.gov/wps/wcm/connect/25bc47ad-d59d-48d6-b90f-4865d1483f4a/Q2-CY2014-Salmonella-Testing.pdf?MOD=AJPERES> (see Table 8a and 8b).

²³ Williams, M.S., et al. (2014). Temporal Patterns in the Occurrence of Salmonella in Raw Meat and Poultry Products and Their Relationship to Human Illnesses in the United States. Food Control 35, 267-273.

performance standards have been appropriately designed, and that no change is necessary.

Comment: As more data become available (and regularly thereafter), several consumer advocacy groups requested that FSIS re-evaluate the performance standards. In addition, comments requested that FSIS assess whether the performance standards need to be updated to account for the actual compliance fraction and other assumptions made during initial calculations. The comments also requested that FSIS periodically measure the impact of the performance standards on public health goals.

Response: FSIS will periodically assess the effect of the performance standards. This assessment will include an estimation of all the parameters used in the risk assessment model and their contribution to a potential reduction in illnesses. FSIS will assess each pathogen reduction performance standard on at least a five-year basis to determine whether the standard should be adjusted. FSIS will calculate ongoing pathogen prevalence for all products subject to standards and will determine whether the pathogen prevalence has been significantly reduced in deciding whether to revise the performance standards.

Comment: A consumer advocacy group requested that FSIS also establish a performance standard for live animals entering the slaughter facility.

Response: FSIS disagrees that it should establish pathogen reduction performance standards for live animals because FSIS does not have jurisdiction on the farm and has not conducted testing on live animals. However, FSIS does recommend that establishments develop pathogen prevention targets for products derived from live animals that an establishment would apply as early as safely possible in its slaughter process. Sampling at this early stage would enable an establishment to determine whether its food safety system is adequately designed to mitigate the incoming load of pathogens.

The rehang or pre-evisceration sampling point used in the FSIS carcass baseline best represents the contamination on the carcass before there is secondary contamination from the evisceration process. FSIS provides information to industry on median indicator organism values at rehang in its compliance guide, "Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry" (June 2015).²⁴ When an

²⁴ Available at <http://www.fsis.usda.gov/wps/wcm/connect/a18d541e-77d2-40cf-a045-b2d2d13b070d/Microbiological-Testing-Raw-Poultry.pdf?MOD=AJPERES>

establishment compares its rehang or pre-evisceration sample results to the ones in the table in the compliance guide, a sample value that is higher than the corresponding one listed in the table indicates that the incoming bacterial load on the bird may be higher than expected, and that the establishment may not be able to maintain process control. As a result, the establishment would be less likely to meet the applicable performance criteria.

Comments: An organization representing the chicken industry urged FSIS to not apply the performance standard for raw chicken parts to any products not consistently sampled in the Raw Chicken Parts Baseline Survey. The organization stated that FSIS has no basis for concluding that the Raw Chicken Parts Baseline Survey is applicable to parts that were marinated with a clear solution. If the Agency has a means to identify which samples in the Survey were from marinated parts, the organization requested that FSIS remove those samples from its calculations.

In addition, the organization stated that necks and giblets should not be subject to a pathogen reduction performance standard because they are typically sold to (and used by)

consumers differently than breasts, legs, and wings. However, several consumer advocacy groups requested that FSIS apply the pathogen reduction performance standard for raw chicken parts to necks, giblets, half carcasses, quarter carcasses, and parts injected or marinated with a clear solution until the Agency has developed a pathogen reduction performance standard specific to those items.

A consumer advocacy group requested that FSIS establish a sampling program for raw chicken livers. The group cited a CDC report detailing outbreaks linked to the consumption of chicken livers²⁵ as support for its request. The group also requested that FSIS sample and develop pathogen reduction performance standards for raw turkey parts because turkey parts are commonly purchased by consumers.

Response: As FSIS explained in the January 2015 Federal Register notice, during the baseline some inspection personnel sampled parts that were injected with a solution or otherwise marinated (80 FR at 3943). Because FSIS did not identify the samples as injected or otherwise marinated at the time of collection, FSIS is unable to remove these results from its

²⁵ Available at <http://www.cdc.gov/salmonella/heidelberg-chickenlivers/011112/index.html>.

calculations and will apply the performance standards to marinated, injected, tumbled, or tenderized parts. For its ongoing exploratory sampling of parts, FSIS issued instructions to inspection program personnel to make explicit that such parts are to be sampled.²⁶ Based on the first 3-4 months of exploratory chicken parts sampling, Salmonella results for injected, tenderized, or vacuum tumbled parts were not significantly higher than those for intact parts. These products are available to the consumer and do present a risk of exposure. FSIS does not believe it appropriate to set a different pathogen reduction performance standard for these products than for other parts.

FSIS will not, however, apply the pathogen reduction performance standard for raw chicken parts to necks, giblets, half carcasses, and quarter carcasses at this time. In FY2016, FSIS will begin exploratory sampling of necks, giblets (i.e., gizzards, hearts, and livers), half carcasses, and quarter carcasses to better understand the prevalence of Salmonella and Campylobacter in these parts. FSIS will post the aggregate results of this testing as part of its Salmonella reporting. In addition, FSIS plans to analyze these data to better understand

²⁶ FSIS Notice 16-15; available at <http://www.fsis.usda.gov/wps/wcm/connect/5233e84c-f4a6-4959-b861-926a4d912eff/16-15.pdf?MOD=AJPERES>

the potential differences in contamination for gizzards, hearts, and livers.

FSIS will use these data to determine whether further sampling is needed. Such information could then be used by the Agency to decide whether pathogen reduction performance standards for these products are necessary.

Comment: An organization representing the chicken industry opposed FSIS using the more sensitive, enrichment-based method for Campylobacter testing that the Agency is using for comminuted product and chicken parts because, according to the commenter, the method increases the likelihood of establishments not meeting the performance standard when actual prevalence may not have changed.

Several consumer advocacy groups requested that the performance standard for Campylobacter in NRTE comminuted chicken and turkey be based on the most sensitive enrichment-based testing method.

Response: In 2013, FSIS began testing NRTE comminuted poultry for Campylobacter using a direct plating method (1 mL test portion). Later, in August 2015, FSIS began concurrently analyzing all NRTE comminuted poultry samples for Campylobacter using the direct plating method and an enrichment-based method

(30 mL test portion).²⁷ The Agency took this step because the enrichment-based method can detect a higher percent of positive samples, as determined from the results of an analysis comparing the direct plating method with the enrichment-based method.

FSIS found that the 1 mL direct plating method identified about 3-4 percent Campylobacter-positive samples for comminuted chicken and about 1 percent Campylobacter-positive samples for comminuted turkey. In contrast, the 30 mL enrichment-based method identified about 15 percent of the samples Campylobacter-positive in comminuted chicken, i.e. about a 4-fold increase in percent positive results between the 30 mL enrichment-based method and the 1 mL direct plating method for comminuted chicken.²⁸ FSIS has not completed a similar evaluation for comminuted turkey.

Regardless, FSIS developed the pathogen reduction performance standards for Campylobacter using a direct plating laboratory method of analysis with a 1 mL test portion. Therefore, FSIS will proceed with assessing establishment performance relative to those standards based on the 1 mL portion size.

²⁷ <http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-updates/archive/2015/ConstUpdate032015>

²⁸ Though comminuted turkey was not tested in this methods comparison, FSIS expects there would also be an increase in the Campylobacter percent positive using the enrichment-based method.

The Agency will continue to perform the 1 mL direct plating method alongside the 30 mL enrichment-based method and analyze data generated from both analytical approaches. These analyses will show whether significant differences exist, and whether these differences support that there is a need to change the combined analytical approach, the pathogen reduction performance standards, and the associated method of analysis for Campylobacter in NRTE comminuted chicken and turkey. If FSIS determines that it needs to change the standards, it will propose changes in the Federal Register.

C. Implementation of Final Performance Standards

Comment: Several industry comments requested that FSIS provide at least a 1- or 2-year transition period after FSIS announces the final performance standards, and before FSIS begins assessing whether establishments meet the standards, to allow industry time to adjust to the new standards.

Response: FSIS does not agree. FSIS notes that the poultry industry has been aware of the FSIS intent to develop pathogen reduction performance standards for chicken parts since at least 2012 when the baseline study got underway. Multiple recent outbreaks for both chicken parts and comminuted poultry heighten the need for industry to collectively address more

optimal process control to limit exposure of the public to pathogens of public health concern. Thus, FSIS is providing a short but practical implementation period sufficient for establishments to adjust their food safety system. FSIS will begin assessing whether establishments meet the new Salmonella and Campylobacter performance standards for NRTE comminuted chicken and turkey and raw chicken parts on [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. This 90-day delay is appropriate because 9 CFR 304.3 provides establishments up to 90 days to validate changes to their food safety system. Consequently, sample results affecting whether establishments meet the new standards begin with the first sample collected as part of a moving window on or after [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN FEDERAL REGISTER]. This 90-day period will effectively provide for a sufficient period of time for establishments to validate that their food safety systems can consistently control for enteric pathogens of public health concern, in accordance with 9 CFR 417.4.

D. Routine Verification Sampling and Testing

Comment: An individual and several consumer advocacy groups stated that routine verification sampling should be unannounced, unpredictable, and completely random to prevent establishments

from temporarily altering their food safety systems to “pass” tests.

In addition, two consumer advocacy groups noted that antimicrobial agents used as interventions in poultry establishments may be masking the presence of Salmonella (i.e., in the neutralizing solution used by the Agency during sample collection) resulting in “false negatives.”

Response: The fact that FSIS no longer collects samples on consecutive days provides establishment less awareness about when a sample is to be collected. FSIS personnel notify establishment management just before collecting each sample that a routine Salmonella and Campylobacter sample is being collected. In addition, FSIS personnel use a method for randomly selecting specific product for sampling such that all product from all shifts, rails, chillers, coolers, and grinders have an equal chance of being selected for sampling.

FSIS has issued instructions to inspection program personnel, directing them to report changes in establishment practices when FSIS samples are collected.²⁹ FSIS has not noted any significant concern with changed production practices during

²⁹ See Chapter VIII, Section II of FSIS Directive 10,250.1; available at <http://www.fsis.usda.gov/wps/wcm/connect/ebf83112-4c3b-4650-8396-24cc8d38bf6c/10250.1.pdf?MOD=AJPERES>

FSIS sampling. Further, based on experience in-plant, FSIS does not believe that establishments can readily adjust their food safety systems to eliminate pathogens without such a change being obvious and inconsistent with their routine food safety system or HACCP flow chart. FSIS inspection personnel are present every day and are aware of the design of the food safety system in each establishment.

FSIS continues to work with USDA's Agricultural Research Service to investigate the potential impact of carryover of antimicrobial agents on sampling results. The findings of this research will inform any actions the Agency may take. Regardless, in 2016, FSIS plans to begin evaluating the use of a new buffer solution to reduce the potential impact from carryover of antimicrobial agents. If an effective buffering media is identified, the buffer media will be used by inspection program personnel when sampling poultry carcasses and parts to reduce carryover from the common antimicrobial interventions that may potentially impact sampling results.

Comment: An organization representing the chicken industry and a meat and poultry processor requested that raw chicken parts only be eligible for sampling in the primary producing establishment.

Response: FSIS disagrees with this comment. Establishment handling and processing of raw chicken parts at secondary processing facilities presents additional opportunity for contamination with pathogens, particularly when new source materials are incorporated. Thus, FSIS will continue sampling finished raw chicken parts at slaughter establishments, as well as at those that further process the product. By doing so, exposure of the public to pathogens of public health concern will be reduced at each practical step in the production process. FSIS has issued instructions to its inspection program personnel that make clear that product that is only repackaged and not subject to further reprocessing is not subject to sampling (see Section V, Part D, of FSIS Notice 16-15).³⁰

Comment: An organization representing the chicken industry requested that FSIS provide more detail about how each sample will be collected, where in the process the product will be sampled, and how the products will be tested.

Response: FSIS has issued necessary notices and directives³¹ on this matter and will issue additional instructions as necessary.

³⁰ Available at <http://www.fsis.usda.gov/wps/wcm/connect/5233e84c-f4a6-4959-b861-926a4d912eff/16-15.pdf?MOD=AJPERES>

³¹ See Directive 10,250.1 and FSIS Notices 16-15, 22-15, 23-15, 31-15 and 32-15.

Comment: A consumer advocacy group requested that FSIS verification sampling include raw chicken parts derived from carcasses set aside for in-plant "reprocessing" and "salvage" activities.

Response: Parts derived from "reprocessing" and "salvage" activities most commonly end up as comminuted product or as parts destined for further processing - both of which are subject to FSIS verification sampling and testing. If FSIS finds that these parts are being handled in a manner that consistently circumvents Agency verification testing, FSIS will consider sampling of this product.

Comment: A meat and poultry processor requested that FSIS enumerate all of its Salmonella results and focus its resources on facilities with higher levels of Salmonella and not focus on presence of the pathogen alone.

Response: FSIS agrees that high levels of pathogens should be considered in FSIS sampling considerations and is exploring options for enumerating more samples. However, because the occurrence of any Salmonella poses a potential hazard for consumers, FSIS will continue to primarily focus upon the presence or absence of the pathogen. In addition, based on sampling results from establishments linked to outbreaks, FSIS

has found low level but frequent contamination does contribute to adverse public health outcomes. Furthermore, pathogen reduction through performance standards results in fewer contaminated products overall, regardless of the levels of Salmonella present. Thus, by setting new performance standards for these products that are based on presence or absence testing, FSIS anticipates establishments will adopt practices that will reduce all pathogens in their products, resulting in a greater overall impact on reducing human illnesses associated with FSIS-regulated products than would result from a focus on enumeration.

Comment: A consumer advocacy group suggested that FSIS sample the neck skins of several birds in a flock (defined as one broiler house) immediately after the kill step, as is done in Sweden.

Response: FSIS questions whether such a sampling program would derive different results than those found through other FSIS sampling. Sampling of the neck skins immediately after the slaughter step is one component of Sweden's Salmonella control program which primarily regulates on-farm production. The testing of the neck skins at the time of slaughter is done to verify the effectiveness of on-farm screening activities.

FSIS encourages establishments to determine the incoming pathogen load on live birds to determine whether its processes can effectively address the pathogens. For example, these data could be used by establishments to determine which farms to obtain birds from for slaughtering, and how to schedule the order of flocks or houses of birds to decrease cross contamination during slaughter.

In addition, FSIS requires that slaughter establishments sample most poultry pre-chill (9 CFR 381.65(g)(1))- a valuable source of data about how well an establishment is minimizing contamination with enteric pathogens and fecal material on live birds presented for slaughter and on carcasses throughout the evisceration and dressing process.

Comment: An organization representing the chicken industry requested that FSIS share reserve rinsate (the solution obtained and sent to FSIS laboratories for analysis after mixing/washing product) with establishments at the time of sample collection.

Response: FSIS does not intend to share rinsate with establishments. FSIS is satisfied with the competency of its laboratory personnel and the procedures they implement, which are able to reliably detect pathogens. FSIS encourages establishments to conduct their own sampling rather than rely

upon FSIS sampling results. In fact, FSIS assumes that establishments will choose to increase sampling and testing as a means of verifying process control, and that they are meeting the new pathogen reduction performance standards. FSIS included additional costs associated with increased sampling and testing by establishments in our cost-benefit analysis posted with this notice.

E. Proposed Moving Window Approach for Assessing Process Control

Comment: In lieu of the moving window approach, an organization representing the meat/poultry industry suggested that FSIS consider other alternative approaches to evaluate process control in which observations are weighted; e.g., the exponentially weighted moving average in which observations are weighted with the highest weight given to the most recent data.

Response: While an exponentially weighted moving average could move some establishments out of a failing status more quickly, it would also move some potentially passing establishments into a failing status. Thus, FSIS concludes the equally weighted 12-month moving average is the best approach.

In the January 2015 notice, FSIS stated that 10 would be the minimum number of samples (over 52 weeks) required to assess process control (80 FR at 3947). Upon further consideration,

FSIS has discovered that the proposed minimum number of Salmonella samples for broiler carcasses (10) would effectively equate to a zero tolerance standard. Therefore, FSIS has revised the minimum number of samples to 11 for broiler carcasses only. The following table sets out what FSIS has determined to be the revised minimum number of samples to assess process control for each product class by pathogen.

Product	Max. acceptable percent positive		Minimum number of samples to assess process control	
	<u>Salmonella</u>	<u>Campylobacter</u>	<u>Salmonella</u>	<u>Campylobacter</u>
Broiler Carcass	9.8%	15.7%	11	10
Turkey Carcass	7.1%	5.4%	14	19
Comminuted Chicken (325g sample)	25.0%	1.9%	10	52
Comminuted Turkey (325g sample)	13.5%	1.9%	10	52
Chicken Parts (4 lb. sample)	15.4%	7.7%	10	13

Comment: Commenters opposed assessing poultry carcass performance categories by combining old and new samples because the results are inconsistent and cannot be compared. In addition, a comment noted that some poultry carcass data may be relatively old and not necessarily indicative of current establishment conditions. Rather than combining old and new sample results to assess performance, comments requested that FSIS "reset" the performance standards for poultry carcasses and begin building new datasets.

Response: FSIS agrees that for categorization purposes of individual establishments, category status should be reflective of the most current sample results. Therefore, beginning [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN FEDERAL REGISTER], FSIS will begin web-posting the category status of all establishments subject to the existing poultry carcass pathogen reduction performance standards based on sample results from May 2015 (when FSIS began routine sampling of broiler and turkey carcasses) to the present.

Comment: Several commenters from industry stated that assessing process control in an establishment over 52 weeks, based solely on one FSIS verification sample per week, will not reflect current or very recent conditions in the establishment.

These commenters also requested that FSIS consider supplemental establishment test results and other establishment measures when assessing process control before determining individual establishment category determinations and presumably posting of establishments' name and category.

To facilitate data sharing between establishments and FSIS, several comments provided recommendations for "supplemental data" that could be submitted by establishments, such as Salmonella enumeration data, indicator organism process control monitoring, or corrective actions. If an establishment elects to share data to demonstrate process control, an organization representing the chicken industry suggested that FSIS incorporate those data into the establishment's dataset and assess the establishment based on the most recent 52 samples - whether they are FSIS verification samples or establishment samples. In addition, if FSIS proceeds with web-posting establishment-specific data, several industry commenters requested that the Agency allow establishments to review the data and to provide any comments, objections, or explanations, which could be included with released data.

Response: The concept of data sharing between establishments and FSIS could have merit. This approach could

provide an incentive for establishments to gain better process control of individual production lots whereby microbiological independence and improved lotting practices can be incorporated. For example, establishments performing their own robust sampling and testing of microbiologically independent lots of raw poultry product could use the results to assess whether they are maintaining ongoing process control. In addition, such lotting and sampling could provide valuable data for establishments when making final decisions on product disposition during corrective actions and HACCP decisions in performing pre-shipment review. FSIS intends to find a mechanism for ensuring that these data are available to the public if FSIS decides to supplement its decision making based on these data.

However, there are a number of challenges, such as variation in industry sampling and testing methodologies, collection of on-going establishment data, and data interpretation. Mechanisms need to be identified and implemented to ensure that these non-FSIS data are reliable, and that they remain reliable over time. FSIS intends to make available compliance guidelines for standardizing data collection and reporting.

FSIS, therefore, is considering initiating a pilot project

using volunteer establishments to evaluate the feasibility of the concept. As part of the pilot project, FSIS may request establishment isolates and use them in the same manner as it uses FSIS isolates; data on how the establishment determines and controls risk; and information on corrective actions taken by the establishment when its risk control parameters are not met. If the pilot project is successful, FSIS would then determine how best to use non-FSIS data in Agency decision making. FSIS will make information available to the public on any pilot or any changes to posting as it moves forward.

Comment: A consumer advocacy group requested that FSIS use data collected to evaluate whether establishment performance for different products (e.g., whole carcasses and parts) is correlated.

Response: FSIS disagrees with the suggestion that setting performance standards requires such data because of how samples are collected, and how organisms attach to product. Attachment of the microorganisms, recovery from injury, and other factors impact the detection of pathogens throughout the production process. Consequently, it is appropriate to set pathogen reduction performance standards on different product types at all feasible points in the production process where control can

be exerted and effective (e.g., for carcasses, parts, and comminuted products). Furthermore, process control demonstrated on carcasses may have no bearing on the level of process control demonstrated for parts or comminuted product.

F. Proposed Changes to Categorization System and Web-posting

Comment: An organization representing the chicken industry stated that the proposed categorization system will result in categories that fail to reflect current conditions in the establishment. The commenter stated that an establishment could remain in categories 2 or 3 up to eighteen months after addressing whatever conditions caused the establishment to be classified in the category. Instead of re-categorizing establishments based on their performance over the last six months, as FSIS proposed, the organization requested that FSIS categorize establishments based on the results of a continuous moving window of the last 52 samples and post categories monthly based on the most recent 52-sample dataset. If the most recent 52-sample dataset indicates that the establishment should be moved into a lower category (Category 2 or 3), the commenter stated that FSIS should provide the establishment with an additional two months to provide supplemental data for FSIS to consider before making its final category determination.

An organization representing the turkey industry and a meat/poultry processor stated that because the proposed standards for NRTE comminuted turkey product allow for so few positive results, there would be very little difference between a Category 1 or 3 turkey establishment. The organization also stated that web-posting individual turkey establishment category information will put turkey establishments at a competitive disadvantage relative to chicken product because the proposed performance standards allow for fewer positives for turkey establishments. To demonstrate this point, the industry comments argued that consumers may choose a Category 1 chicken product over a Category 2 turkey product thinking the chicken product is "safer" or "better," when the turkey product may actually have lower numbers of Salmonella. If FSIS proceeds with web-posting establishment-specific data for all eligible turkey establishments, the comments requested that FSIS also post information on the data represented.

An organization representing the turkey industry stated that posting individual establishments' categories has not historically been a substantial factor in driving industry to reduce pathogens. Rather, the organization stated that posting individual establishments' categories may be harmful to industry

and confusing to consumers. Likewise, several industry comments supported posting aggregate data rather than individual establishment-specific data to minimize unintended consequences to industry. An organization representing the chicken industry recommended posting Category 3 establishments only.

An organization representing the meat industry stated improvements in controlling Escherichia coli 0157:H7 in beef were more the result of industry's implementation of new processes and interventions than to public accessibility of establishment-specific data. In addition, for consistency, the organization requested that FSIS outline its Category 1/2/3 posting procedures in the draft Establishment-specific Data Release Strategic Plan.

An organization representing the chicken industry stated that consumers are only able to associate web-posting with branded products. As a result, the organization stated that web-posting would disproportionately harm establishments producing branded products compared to establishments producing non-branded product.

Response: FSIS has decided to re-categorize establishments monthly based on their performance over the last three months. For example, if an establishment has exceeded the Salmonella or

Campylobacter maximum allowable percent positive during any completed 52-week moving window over the last three months, it will be placed in Category 3 at least until establishments are re-categorized a month later.

In addition, because the comminuted chicken and turkey pathogen reduction performance standards permit only one positive result for Campylobacter in order to pass the standard, essentially eliminating Category 2, FSIS will categorize eligible establishments producing these products as either passing or failing. Thus, FSIS has revised its category classification system as follows:

I. Category 1. Consistent Process Control: Establishments that have achieved 50 percent or less of the Salmonella or Campylobacter maximum allowable percent positive during all completed 52-week moving windows over the last three months.

II. Category 2. Variable Process Control: Establishments that meet the Salmonella or Campylobacter maximum allowable percent positive for all completed 52-week moving windows but have results greater than 50 percent of the maximum allowable percent positive during any completed 52-week moving window over the last three months.

III. Category 3. Highly Variable Process Control: Establishments that have exceeded the Salmonella or Campylobacter maximum allowable percent positive during any completed 52-week moving window over the last three months.

IV. Passing. Establishments that meet the Campylobacter maximum allowable percent positive for NRTE comminuted chicken or turkey during all completed 52-week moving windows over the last three months.

V. Failing. Establishments that have exceeded the Campylobacter maximum allowable percent positive for NRTE comminuted chicken or turkey during any completed 52-week moving window over the last three months.

FSIS disagrees that a delay in web-posting should occur if an establishment's performance is trending in an adverse direction. One purpose of the pathogen reduction performance standards is to ensure that industry is taking steps to continuously improve its food safety system. Therefore, FSIS will begin web-posting as follows:

- No sooner than [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN FEDERAL REGISTER], for establishments that produce poultry carcasses and that have the minimum number of samples, FSIS will begin posting individual establishment category status based on sample results from May 2015 (when FSIS began routine sampling of broiler and turkey carcasses) to the present. Thereafter, FSIS will update the category status for each eligible establishment monthly.
- For establishments that produce chicken parts and

comminuted poultry products, FSIS intends to begin web-posting quarterly aggregate information relative to categories beginning about [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN FEDERAL REGISTER]. This information will give industry and other stakeholders timely information about progress being made to reduce contamination in NRTE poultry of all types sampled.

- For all establishments subject to the new pathogen reduction performance standards, after completion of the first 52-week moving window (approximately one year), FSIS will begin posting whether establishments meet the standards, or what category establishments are in, depending on the standard for the particular product, based on FSIS results. However, as is discussed above, based on at least the minimum number of samples to assess process control for that product/pathogen pair and other available information about establishments, such as noncompliance rates, if establishment performance overall does not improve or appears to be worsening before the completion of the first moving window, FSIS may begin web-posting individual establishment category information sooner.

FSIS does not agree that the category approach has not been effective. Our experience with performance standards shows that industry does respond to new pathogen reduction performance standards. For example, the proportion of positive Salmonella carcasses fell after implementation of 1996 Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) final rule but then began to rise in the mid-2000s. FSIS speculates that this rise was because there were rarely significant consequences to failing a Salmonella set. In 2006, this trend of rising Salmonella positive carcasses was reversed when FSIS instituted categorization and web-posting of Category 2 and 3 establishments. In fact, the number of establishments not meeting the standard fell by 50 percent in the 2-year period following the time FSIS started posting category information.

On January 15, 2015, FSIS published a notice in the Federal Register that requested comment on the Agency's draft Establishment-specific Data Release Strategic Plan for sharing with the public data on federally inspected meat and poultry establishments (80 FR 2092). Although outside the scope of this policy initiative, FSIS will consider the issue raised by the commenter as it considers other comments received on the draft Plan.

Finally, FSIS disagrees that web-posting will disproportionately harm establishments producing branded products compared to those producing non-branded product. Any establishment could be potentially affected by the postings because consumers and wholesale buyers in the poultry supply chain can equally view the Web site. Therefore, it is in any establishment's interest, whether branded or non-branded, to put the processes in place to ensure that it meets or exceeds the pathogen reduction performance standards.

Comment: A consumer advocacy group requested that FSIS post aggregate data for Campylobacter in imported poultry products and post aggregate reports showing the Category 1/2/3 distribution for each product class.

Response: FSIS disagrees with the comment because FSIS does not collect enough samples from individual foreign establishments to assess whether they meet the standards. The foreign government conducts verification activities at the foreign establishment to make that type of determination. Through records reviews and audits, FSIS verifies that foreign inspection systems include these types of verification activities.

FSIS plans to develop and implement a voluntary pilot

project to explore mechanisms for reporting aggregate data specific to foreign countries that export NRTE poultry to the United States. FSIS will continue to verify whether those governments assess individual establishment process control as part of the equivalency process.

H. Enforcement

Comment: Several consumer advocacy groups stated that certain serotypes of Salmonella should be considered adulterants. The comments cited other actions that FSIS should take to enforce the performance standards, including suspending inspection at facilities that do not meet a performance standard until the establishment meets the standard and recommending the recall of product produced during periods when the establishment has inadequate process control.

Response: FSIS disagrees with the comment. The pathogen reduction performance standards are not lot-release standards. Product produced by an establishment that does not meet the standard is not necessarily adulterated. However, failing to meet the standard provides evidence that the production process is not well controlled, and FSIS will take steps to ensure that the establishment improves its production process to reduce variability and to gain more consistent process control. FSIS

does agree that persistent failure to meet the pathogen reduction performance standards can be used as a rationale to progressively encourage the establishment to implement more effective food safety system controls or to discontinue production of product.

In May 2011, the Center for Science in the Public Interest (CSPI) petitioned FSIS to issue an interpretive rule to declare certain strains of antibiotic-resistant (ABR) Salmonella to be adulterants in raw ground meat and raw ground poultry.³² On July 31, 2014, FSIS denied the petition without prejudice because the Agency concluded that the data do not support giving the four strains of ABR Salmonella identified in the petition a different status as an adulterant in raw ground meat and raw ground poultry than Salmonella strains that are susceptible to antibiotics.³³ The Agency concluded that additional data on the characteristics of ABR Salmonella are needed to determine whether certain strains of ABR Salmonella could qualify as adulterants under the Federal Meat Inspection Act and Poultry Products Inspection Act. On October 14, 2014, CSPI refiled its petition to provide additional data and requested that FSIS

³² http://www.fsis.usda.gov/wps/wcm/connect/04cb5fad-c13e-4de7-b391-acd95191a95/Petition_CSPI_052511.pdf?MOD=AJPERES

³³ <http://www.fsis.usda.gov/wps/wcm/connect/73037007-59d6-4b47-87b7-2748edaa1d3e/FSIS-response-CSPI-073114.pdf?MOD=AJPERES>

declare certain strains of ABR Salmonella adulterants in all raw meat and raw poultry products. FSIS is evaluating the new request.

Comment: A consumer advocacy group requested that FSIS instruct inspection personnel on when and how to increase enforcement at facilities that do not meet the performance standards. In addition, the commenter requested that FSIS initiate increased enforcement action when an establishment repeatedly fails to meet the performance standard.

Response: FSIS recently revised FSIS Directive 5100.4³⁴ to provide instructions to its personnel on how to conduct a PHRE. Enforcement, Investigations, and Analysis Officers (EIAOs) will conduct a PHRE (in priority order) at every establishment that does not meet a performance standard (i.e., the establishment is in Category 3); at establishments that have produced products with repetitive Salmonella serotypes of public health concern, indicating potential higher risk for being identified as contributing to an outbreak; and establishments with Salmonella PFGE patterns matching those found in recent outbreaks or

³⁴ Available at <http://www.fsis.usda.gov/wps/wcm/connect/6c30c8b0-ab6a-4a3c-bd87-fbce9bd71001/5100.4.pdf?MOD=AJPERES>

epidemiological evidence linking them to illness to determine the need for a FSA. If, during the PHRE, the EIAO determines that the establishment is shipping or producing adulterated product, operating without a HACCP plan, or engaging in any other type of non-compliance that supports taking a withholding or suspension action without prior notification (9 CFR 500.3), the EIAO will take immediate steps to stop the wrongful practice. Next, the EIAO will consult with the District Office (DO) to determine whether additional enforcement action is needed. For an EIAO to recommend that the DO issue a NOIE, he or she must support that the conditions in the establishment, or the actions of establishment personnel, constitute a situation that would justify the action under 9 CFR 500.4, and that such conditions have resulted in adulterated product or create insanitary conditions that could cause product to be adulterated.

As stated above, if, after 90 days, the establishment has not been able to gain process control, as determined from FSIS's follow-up sampling and from the results of the PHRE or FSA, and the establishment has not taken corrective actions, FSIS will likely take enforcement actions, such as by issuing a NOIE or by suspending inspection, under the conditions and according to the

procedures described in 9 CFR Part 500. FSIS will not issue an NOIE or suspend inspection based solely on the fact that an establishment did not meet a performance standard.

Comment: A consumer advocacy group requested that FSIS refuse entry of imported raw poultry product that FSIS finds positive for Salmonella. On the other hand, an organization representing the chicken industry stated that denying entry of imported products (or determining foreign country equivalency) based on import verification sampling results may result in international trade ramifications.

Response: Salmonella is not an adulterant in NRTE poultry products. Therefore, a positive test result for Salmonella in imported NRTE poultry product sampled by FSIS import inspection personnel would not result in regulatory control actions at port-of-entry (i.e., refused entry of the product). However, foreign countries that are eligible to export poultry products to the United States must apply inspection, sanitation, and other standards that are equivalent to those that FSIS applies to poultry products. Thus, in evaluating whether a foreign country maintains an equivalent inspection system to that of FSIS, FSIS considers whether the country's pathogen reduction performance standards, testing, and other verification

procedures related to Salmonella or Campylobacter are equivalent to those that FSIS uses.

I. Other Agency Actions

Comment: A consumer advocacy group requested that FSIS make detailed testing data available to public health officials (e.g., through PulseNet).

Response: FSIS routinely shares subtyping data for positive samples with public health officials for data analysis, interpretation, and application. This sharing includes submission of serotype and PFGE data to Pulsenet and antimicrobial resistance data to the National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS). FSIS has also recently begun using whole genome sequencing to analyze positive isolates in certain cases and will continue to expand this testing as resources allow. FSIS is submitting this sequencing data to the National Center for Biotechnology Information, a publically accessible database.

Comment: An organization representing the meat industry requested that FSIS evaluate the correlation between higher sanitary dressing noncompliances and the probability of positive sample results in poultry products, as it did for beef products.

Response: FSIS will assess this issue and report its findings in FY2016. Meanwhile, outbreaks associated with Salmonella in raw poultry products continue. Improvement in sanitary dressing and other process controls can reduce the levels of Salmonella and other enteric bacteria, such as Campylobacter, on poultry carcasses. Therefore, FSIS believes that establishments should focus more closely on their sanitary dressing and process control procedures to prevent carcass contamination. Importantly, the recent final rule on poultry inspection modernization mandates that establishments prevent contamination of poultry product with feces throughout the slaughter and dressing operation rather than permit carcasses to be contaminated and then reconditioned (9 CFR 381.45(g)).

Comment: An organization representing the meat/poultry industry requested that FSIS explain how the Agency intends to assess whether the raw beef follow-up sampling model (i.e., either 16 or eight follow-up samples will be collected when an establishment does not meet the standard) is working for Salmonella and Campylobacter testing, and, if changes are made, how FSIS plans to communicate the changes to industry.

Response: FSIS has found follow-up sampling to be effective at finding additional positives in raw beef samples. FSIS will

analyze the data and information collected during follow-up sampling (which will be part of the moving window sampling) of poultry and make any necessary changes to the follow-up sampling procedures based on that analysis.

Comment: A consumer advocacy group requested that FSIS include improving poultry welfare and living conditions and protecting bird health in its recommended pre-harvest strategies for producers for controlling Salmonella and Campylobacter. The group stated that research has shown that environmental stresses (e.g., depriving a bird of feed, overcrowding) can result in increased incoming poultry pathogen loads.

Response: FSIS agrees with the comment. FSIS has reviewed available information, including the information provided by the commenter, regarding the impact of animal welfare and living conditions on food safety. FSIS has updated the Compliance Guideline for Controlling Salmonella and Campylobacter in Raw Poultry to include interventions and best practices that should assist producers in providing for animal welfare, living conditions, and bird health at pre-harvest, which should in turn minimize stress in poultry and reduce pathogens in birds presented at slaughter.

Comment: An organization representing the chicken industry

stated that a shift from Category 1 to Category 2 does not warrant a for-cause FSA because Category 2 establishments are technically meeting the standard. The organization requested that FSIS outline situations in which verification sampling would trigger a for-cause FSA and clarify what the Agency means by a "higher number of positives."

The same organization also opposed FSIS conducting for-cause FSAs when it finds serotypes of public health significance because, according to the organization, doing so would effectively impose a zero-tolerance standard for these serotypes. The organization argued that using this approach would encourage establishments to focus only on certain serotypes rather than manage overall pathogen levels through a process control program.

Response: FSIS will not typically schedule an FSA based on an establishment moving from Category 1 to Category 2. As mentioned above, during the PHRE, EIAOs use the decision-making process outlined in FSIS Directive 5100.4 to determine whether the DO needs to schedule an FSA.

FSIS will focus on Salmonella serotypes of public health concern because the incidence rate of infection by these serotypes is higher than for other serotypes. Moreover, for-

cause PHREs in response to serotypes of public health concern will in fact stimulate improvement in industry performance in controlling Salmonella generally.

As for "higher number of positives," FSIS intends to analyze results of the routine sampling to identify data trends indicative of an establishment moving in an adverse direction. Once identified, these trends may prompt FSIS to conduct a PHRE or take other appropriate actions, such as additional sanitary dressing verification procedures, at the establishment that produced the product. FSIS provides Salmonella serotype results to establishments to facilitate their efforts in identifying the appropriate intervention.

FSIS is concerned that there is a misguided belief that new products do not need to be produced in a manner to reduce the presence of pathogens of public health concern. Since the 1996 PR/HACCP final rule, FSIS has stressed that properly operating food safety systems are designed to reduce the presence of pathogens of public health concern.

J. Cost-benefit Analysis

Comment: Factoring in the costs of the additional FSAs and follow-up sampling associated with the high percentage of establishments not expected to initially meet the new standards,

an organization representing the meat industry questioned how FSIS does not expect to incur any additional costs as a result of setting new performance standards. The organization requested that FSIS calculate the number and cost of FSAs and follow-up samples the Agency expects to collect for the first three years after the changes are implemented. Other more general comments stated that the proposed changes would be overly resource intensive or potentially cost prohibitive for FSIS.

Response: To account for the sampling and enforcement actions associated with the new performance standards, FSIS will realign resources, rather than allocating any additional resources beyond what it currently budgets. FSIS will examine the following in a retrospective analysis to realign resources: the allocation of sampling and outcome of FSAs initiated as a result of the new pathogen reduction performance standards.

In addition, FSIS has updated its FSA methodology by shortening the timeline for completion of most FSAs from 2 to 4 weeks to 5 to 7 production days.³⁵ This change will enable FSIS personnel to perform a greater number of FSAs each year, thereby improving Agency efficiency.

³⁵ FSIS Directive 5100.1, Revision 4; available at: <http://www.fsis.usda.gov/wps/wcm/connect/31bb8000-fb33-4b51-964b-1db9dfb488dd/5100.1.pdf?MOD=AJPERES>

COST-BENEFIT ANALYSIS

FSIS has considered the economic effects of new pathogen reduction performance standards for Salmonella and Campylobacter in NRTE chicken parts and comminuted poultry. FSIS published a preliminary cost-benefit analysis in support of the January 2015 Federal Register notice in which FSIS proposed the new performance standards and sought comment on the estimates and the methodology used.³⁶ After reviewing the comments received, FSIS updated the cost benefit analysis to reflect a change in a cost assumption. In addition to making changes to their production processes in order to meet the new pathogen reduction performance standards, FSIS originally assumed that only 30, 40, or 50 percent of establishments that fail to meet the performance standard would re-asses their HACCP plan. However, FSIS now assumes that all, or 100 percent, of establishments that fail to meet the standard will re-assess their HACCP plans to comply with 9 CFR 417(3)(b). A summary of the analysis follows. The full analysis is published on the FSIS Web site as supporting documentation to this notice.

Industry Costs

³⁶ Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards Preliminary Cost-Benefit Analysis; available at: <http://www.fsis.usda.gov/wps/wcm/connect/e146ef97-c269-44ee-bea2-0c04fcc6f463/CBA-Chicken-Parts-Comminuted.pdf?MOD=AJPERES>.

Establishments will incur costs as they make changes to their processes to meet the new standards. FSIS estimates that approximately 63 percent of raw chicken parts producing establishments, 62 percent of NRTE comminuted chicken producing establishments, and 58 percent of NRTE comminuted turkey producing establishments will not meet the new Salmonella standards. FSIS estimates that approximately 46 percent of raw chicken parts producing establishments, 24 percent of NRTE comminuted chicken producing establishments, and 9 percent of NRTE comminuted turkey producing establishments will not meet the new Campylobacter standards.

Establishments that initially do not meet the standard but that choose to do so will need to make changes to their production processes to lower the prevalence of Salmonella and Campylobacter in their products. Changes made by poultry slaughter establishments could include pre-harvest interventions, such as vaccination programs; well-timed feed withdrawal; clean and dry litter and transportation; and supplier contract guarantees of pathogen-free flocks. During processing, establishments could add additional cleaning procedures, apply chemical antimicrobial agents to parts and source materials for comminuted poultry product, and provide

additional sanitation training to employees. For the purposes of the cost-benefit analysis, FSIS used the cost of adding antimicrobial agents to poultry parts as a proxy for the costs of interventions and changes that could be implemented. FSIS used this approach based on information from FSAs in response to broiler Salmonella sets not meeting the standards and information from the FSIS Poultry Checklist. Through FSAs, FSIS has found that the majority of establishments added antimicrobial agents to the production process as a corrective action, suggesting that an antimicrobial intervention would be the most likely response should an establishment not meet the proposed performance standards. Also, information from the FSIS Poultry Checklist showed that the majority of establishments are not applying antimicrobial agents to raw poultry parts and source materials for comminuted poultry product.

FSIS accounted for uncertainty in the proportion of establishments making changes to their production processes by providing a range of 30, 40, and 50 percent (of establishments initially falling short of but eventually meeting the standards in two years) for cost estimates for capital equipment, antimicrobial agents, and microbial sampling. For HACCP plan re-evaluation and training costs, FSIS assumes that all

establishments (100 percent) that do not meet the standard will re-evaluate their HACCP plan. These costs are summarized and annualized over 10 years at a discount rate of 7 percent in Table 1.

Table 1. Total Industry Costs Annualized¹

Compliance Level of Establishments Not Meeting Standard	Cost Component	Primary Estimate (\$mil)	Low Estimate (\$mil)	High Estimate (\$mil)
30%	Capital Equipment	2.15	-	-
	Antimicrobial Agent	6.54	4.61	8.46
	Microbiological Sampling	9.27	6.18	12.36
	HACCP Reassessment & Training	*	-	-
Total Costs		17.96	12.94	22.97
40%	Capital Equipment	2.86	-	-
	Antimicrobial Agent	8.72	6.14	11.28
	Microbiological Sampling	9.82	6.52	13.05
	HACCP Reassessment & Training	*	-	-
Total Costs		21.41	15.52	27.19
50%	Capital Equipment	3.58	-	-
	Antimicrobial Agent	10.89	7.68	14.12
	Microbiological Sampling	10.40	6.91	13.81
	HACCP Reassessment & Training	*	-	-

Total Costs	24.88	18.17	31.51
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¹ Costs annualized at a discount rate of 7 percent over 10 years.

*Approximately \$12,216, a value too small to display in table.

Agency Costs

FSIS will not request additional funding as a result of introducing new performance standards. FSIS allocates a fixed number of samples by product class, sampling project, and pathogen each year. The two major components of the pathogen reduction performance standards - product sampling and follow-up actions - will be implemented in such a way that they are resource neutral. FSIS is not expanding the number of samples it will analyze. Instead, it will reallocate samples from other programs, specifically the young chicken and turkey sampling programs for Salmonella and Campylobacter, as FSIS moves towards assessing performance using a moving window (described above) of sampling results. FSIS does not anticipate the need to exclude any of the other testing programs allocated to other product classes. FSIS intends to test carcasses at the level that is needed to document establishment performance status. Furthermore, enforcement actions taken as a result of the new performance standards, namely FSAs, will not require additional FSIS resources. FSIS has updated its FSA methodology and has shortened the timeline for the completion of most FSAs

from 2 to 4 weeks to 5 to 7 production days.³⁷ The shortened FSA will enable FSIS Enforcement, Investigations and Analysis Officers to perform more FSAs each year. Therefore, FSIS will not expend additional resources to implement the proposed performance standards.

Public Health Benefits

As establishments make changes to their production processes and reduce the prevalence of Salmonella and Campylobacter in chicken parts and NRTE comminuted poultry, public health benefits will be realized in the form of averted illnesses. For each assumed compliance level FSIS estimated the cost savings associated with the percentage reduction in human illnesses as calculated in the 2015 Risk Assessment. The results of this calculation were annualized over 10 years at a discount rate of 7 percent and are displayed in Table 2.

Table 2. Public Health Benefits Annualized¹

³⁷ FSIS Directive 5100.1, Revision 4; available at: <http://www.fsis.usda.gov/wps/wcm/connect/31bb8000-fb33-4b51-964b-1db9dfb488dd/5100.1.pdf?MOD=AJPERES>

Compliance Level of Establishments Not Meeting the Standard	Primary Estimate (\$mil)	Low Estimate (\$mil)	High Estimate (\$mil)
30%	50.87	31.84	79.89
40%	79.66	50.43	125.89
50%	109.10	68.80	171.24

¹Benefits annualized over 10 years at a discount rate of 7 percent.

Summary of Net Benefits

Table 3 displays the total costs and benefits expected from the implementation of performance standards for chicken parts and comminuted poultry. All values have been annualized over 10 years at a 7 percent discount rate. For all compliance levels considered, the performance standards result in net benefits.

Table 3. Summary of Net Benefits¹

Compliance Level of Establishments Not Meeting the Standard	Cost/Benefit Component	Primary Estimate (\$mil)	Low Estimate (\$mil)	High Estimate (\$mil)
30%	Industry Costs	(18.0)	(12.9)	(23.0)
	FSIS Costs	-	-	-
	Public Health Benefits	50.9	31.8	79.9
Net Benefits		32.9	18.9	56.9
40%	Industry Costs	(21.4)	(15.5)	(27.2)
	FSIS Costs	-	-	-
	Public Health Benefits	79.7	50.4	125.9
Net Benefits		58.3	34.9	98.7
50%	Industry Costs	(24.9)	(18.2)	(31.5)
	FSIS Costs	-	-	-
	Public Health Benefits	109.1	68.8	171.2

Net Benefits	84.2	50.6	139.7
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¹All costs and benefits annualized over 10 years at a 7 percent discount rate.

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Done at Washington, DC on: February 4, 2016.

Alfred V. Almanza,

Acting Administrator.

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